

# Diagnostic Accuracy of the Vulvoscopy Index for Detection of Vulvar Dermatoses (DATRIV Study, Part 1)

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**Abstract:** Three rings vulvoscopy (TRIV) has previously been described to facilitate the diagnosis and treatment of vulvar discomfort. The distinction between outer, middle, and inner vulvar rings is based on differences in anatomy, histology, and embryology. The vulvoscopy index was designed considering the patient's history, clinical exam, and assessment of the specificity and localization of the lesion relative to the vulvar ring. This paper evaluated the sensitivity, specificity, and diagnostic accuracy of the vulvoscopy index in detecting vulvar dermatosis compared with histopathology as a reference test. Structured ISSVD vulvodynia pattern questionnaire and TRIV form data were utilized for the study. The data obtained were analyzed using StatSoft (Dell, Austin, Texas), Statistica 12 (TIBCO®, Palo Alto, CA), and SPSS 20 (IBM, Armonk, NY). Ethical approval for the study was obtained from the Institutional Review Board of Polyclinic Harni, and all patients provided written informed consent. The histopathological diagnosis of vulvar dermatosis was confirmed in 72 patients at first biopsy. Lesions specific for vulvar dermatosis were visible by TRIV in 82 patients. The resulting difference of ten patients were participants with early vulvar dermatosis. In six of them, vulvar dermatosis was confirmed at a later biopsy during the study period. There was no statistically significant difference between the scores of points (median and range), frequency and relative frequency of vulvar findings within one item of the vulvoscopy index and histopathology, except for ten patients with early forms of vulvar dermatoses. The sensitivity, specificity, and diagnostic accuracy of the vulvoscopy index for detecting vulvar dermatosis were 100%, 96.1%, and 96.9%, respectively. The positive and negative predictive values were 0.88 and 1.00, respectively. The vulvoscopy index represents a compelling clinical test for detecting vulvar dermatoses. Differences between vulvoscopic and histopathological diagnostics implicate the impossibility of histopathology in recognizing early forms of vulvar dermatoses. Accordingly, early dermatoses could represent a key area for applying this test. ClinicalTrials.gov Identifier: NCT02732145.

**Keywords:** Vulvar Dermatoses, Vulvoscopy, Three Vulvar Rings, Three Rings Vulvoscopy, Vulvoscopy Index

## 1. Introduction

Colposcopic examination of the vulva was clinically and scientifically accepted as a diagnostic method in vulvology during the 1980s. However, monitoring vulvar lesions under colposcopic light and magnification began a decade earlier.

Acceptance of this approach to the vulva received full confirmation during the 1990s when this diagnostic method was called vulvoscopy [1]. The basic principle of vulvoscopy is the consideration of vulvar lesions through the complex anatomy, histology and embryology of the vulva as lesions of similar appearance in various parts of this zone may have

different clinical significance [2-6]. The clinical relevance of vulvoscopy in women with chronic vulvar discomfort was first declared approximately three decades ago [7].

The wide acceptance of vulvology introduced a new multidisciplinary approach to vulvar diseases. According to the International Federation for Cervical Pathology and Colposcopy (IFCPC) and the International Society for the Study of Vulvovaginal Disease (ISSVD) in 2011, the latest classification of vulvar disorders has introduced a detailed description of vulvar lesions with dermatological criteria. Its implementation in daily gynecological practice brings additional efforts in assessing and planning the treatment of vulvar lesions [8].

Evidence-based practice delays in the field of vulvovaginal conditions and the lack of validated outcome measures obstruct the implementation of interventional clinical trials for vulvovaginal diseases [9].

In order to provide a context for collecting more data on chronic vulvar disorders, such as vulvar dermatoses, an analysis of the complex structure of the vulva has been previously published [10, 11]. This paper described an original colposcopic technique called three-ring vulvoscopy (TRIV) for a vulvar examination. According to anatomical, histological and embryonic nature, the described approach distinguishes three different zones or rings of the vulva (*Figure 1*).

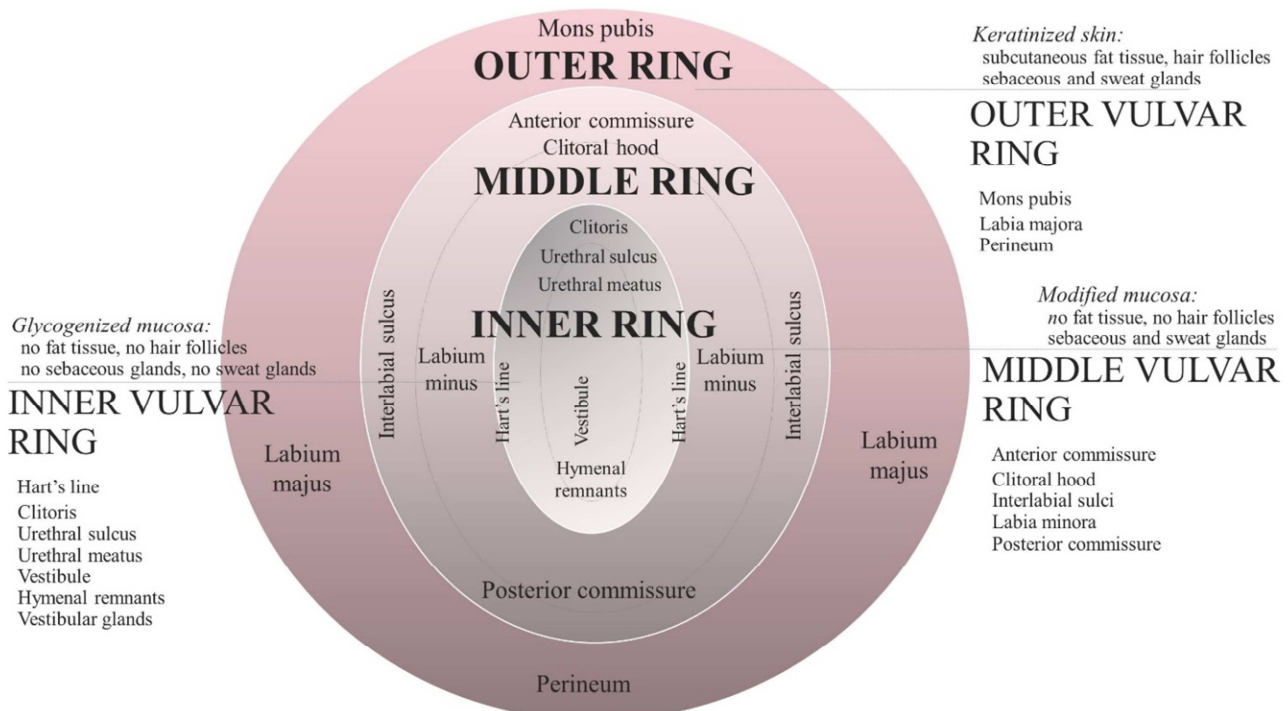
Vulvar skin of ectodermal origin forms the outer vulvar ring, including the pubis, labia majora and perineum. These

structures consist of a keratinized hair-bearing epidermis containing sebaceous, apocrine, and eccrine glands; subcutaneous fat; and blood vessels in the underlying dermis.

The modified mucosa builds a middle vulvar ring consisting of an anterior commissure with clitoral hood, interlabial sulci, labia minora, and posterior commissure. It is covered with hairless skin that contains sebaceous glands without subcutaneous fat. The epithelial structure of the middle ring is of ectodermal origin, and the underlying tissue developed from the mesoderm. The demarcation line between the outer and middle ring of the vulva is formed by the hairline.

Glycogenized, unpigmented, squamous mucosa of endodermal origin represents the histological basis of the inner vulvar ring. It includes the clitoris, urethral sulcus, urethral meatus, hymenal remnants, the opening of the Bartholin's gland, Hart's line, and vestibule. The demarcation line between the inner and middle ring is marked by the junction of keratinized and nonkeratinized epithelium on the internal aspects of the labia minora, called Hart's line.

The lower genital tract includes the vulva, groin, perianal area and anus. The skin of the groin and perianal area consists of the same tissue as the skin of the outer vulvar ring, which is why lesions of these regions can be described in the same way as lesions of the outer ring of the vulva. Endoscopy or colposcopy of the anus is commonly known as high-resolution anoscopy.



**Figure 1.** Three vulvar rings.

To simplify the morphological evaluation of lesions, the current terminology of abnormal findings has been adapted by describing the lesions according to the recommended general principles [8, 12]. Lesions with the secondary morphological presentation were called "specific lesions" [7,

13], and their localization was described in relation to three vulvar rings [10, 11]. Despite prior studies, this domain still lacks a relevant criterion for objective evaluation of results as standards in outcome measures are key to optimizing patient diagnosis and treatment. [14, 15].

The DATRIV study aimed to create a basis for developing standard outcome measures in vulvoscopy. For this purpose, two index tests based on the specificity and localization of the vulvar lesion concerning three vulvar rings were designed as outcome parameters. The clinical value of both tests was assessed in correlation with histopathology as a reference test. The first part of the study encloses clinical data linked to the vulvoscopy index.

## 2. Methods

### 2.1. Study Design

The DATRIV study was designed as a prospective

experimental study with diagnostic interventions. An asymptomatic patient was randomly assigned to each symptomatic patient. Exclusion criteria were vulvar infection, benign tumors, pre-/malignancy, incomplete medical records and protocol violation. The research was conducted at Polyclinic Harni in Zagreb, Croatia, from December 1, 2011, to December 31, 2016.

The study enclosed a total of 328 consecutive participants (Figure 2). According to the patient history and the ISSVD Vulvodinia Pattern Questionnaire, the asymptomatic group without vulvar difficulties (N=164) and the symptomatic group with chronic vulvar discomfort (N=164) were distinguished. [16].

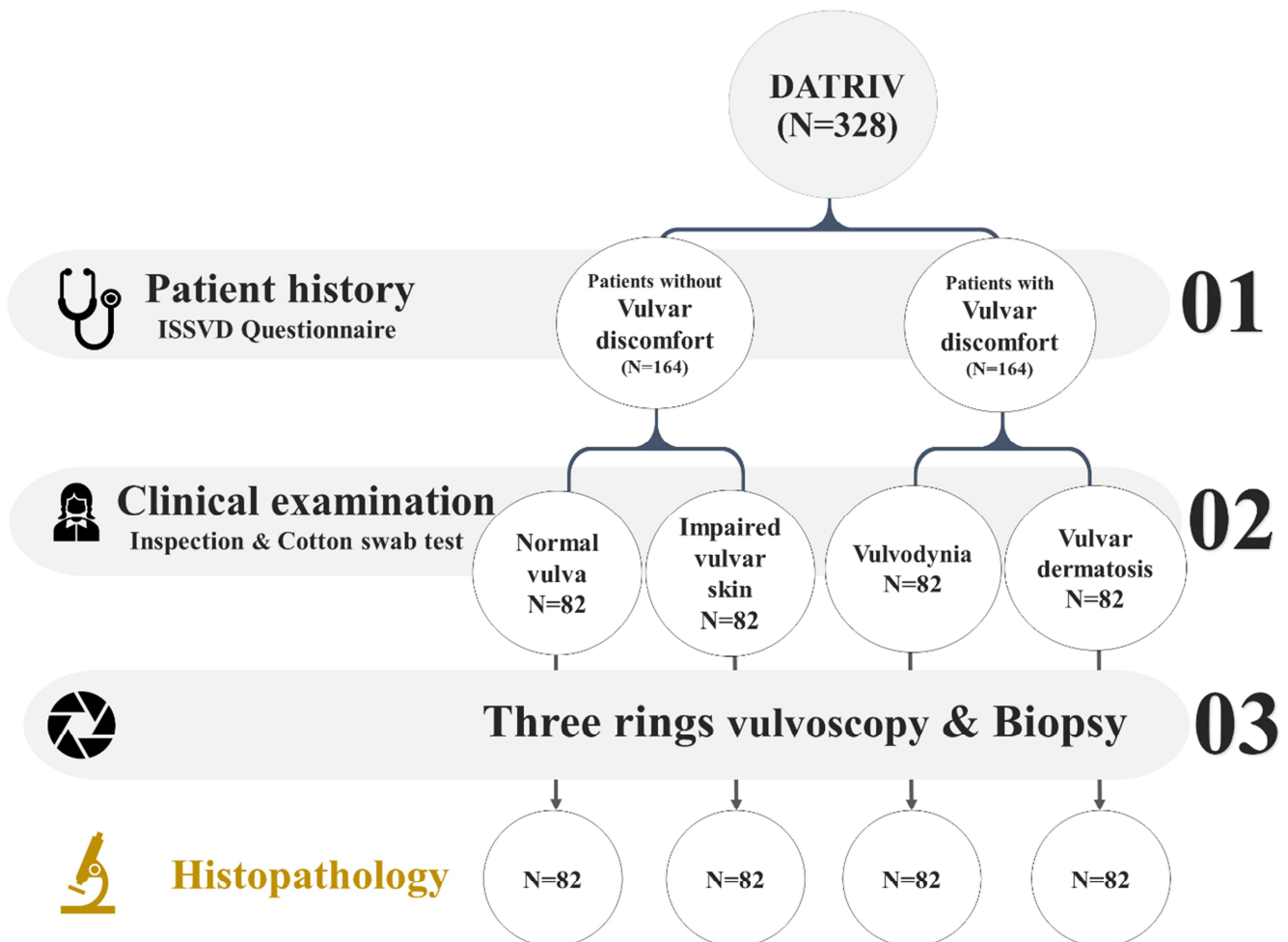


Figure 2. STARD Flow Diagram.

Based on clinical examination, including an inspection and cotton swab test, asymptomatic participants were classified into the subgroup normal vulva (N=82) if there were no changes of the vulva or impaired vulvar skin (N=82) if nonspecific changes of the vulva were observed. The definition of the normal vulva was adopted from prior vulvoscopy classifications [7, 8, 12, 13]. Nonspecific findings comprised nonspecific erythema in any part of the vulva, punctuations and papillae, paleness, smoothness, and fissures of the vulvar mucosa. These were formerly described

as findings suggesting an infectious and viral pathology [13].

Patients with chronic vulvar discomfort were categorized into two subgroups, patients with vulvodinia (N=82) and patients with lesions of the vulva specific for vulvar dermatosis (N=82). Vulvodinia was diagnosed following Friedrich's criteria according to existing classification [17-19]. The vulvar lesions found in patients with vulvodinia were irrelevant to the vulvodinia diagnosis. "Specific lesions" implied a finding of an eczematous inflammation with thickened, excoriated skin (red, flat, and diffuse lesions

presenting on the vulvar skin); hypopigmented or white lesions (irregularly and extensively diffuse white plaques and patches on skin and mucosa); white reticular pattern to extensive erosion especially in the vestibule; erythematous papules with silver, scaly plaques, agglutination and fusion; or resorption of the labia minora and clitoral hood, loss of vulvar architecture, and sclerotic changes [7, 13].

TRIV and vulvar biopsy with histopathology as diagnostic interventions were performed in all four groups of patients. A TRIV data form was designed to collect and organize vulvoscopy data.

The vulvar biopsy in symptomatic patients was performed as part of routine clinical care. Asymptomatic participants were recruited from asymptomatic women who had undergone planned labiaplasty, and the vulvar biopsy was performed on vulvar samples granted for further investigation.

## 2.2. Vulvoscopy Index

To create an initial database of practical tests for

measuring vulvoscopy results, a vulvoscopy index and an N-S-P scheme were developed, as quality measuring of a medical procedure suggests its importance in the hierarchy of diagnostic methods. The clinical value of both tests was estimated regarding histopathological diagnosis as the gold standard in diagnosing vulvar dermatoses. This paper presents the diagnostic value of the quantitative test called the vulvoscopy index.

The vulvoscopy index is founded on five categories (Figure 3):

- Vulvar discomfort (absent=0; present=4 points).
- Marinoff index (negative/Marinoff 0=0; positive/Marinoff 1 or 2=3 points).
- Cotton swab test (negative=0 and positive=2 points).
- Localization of the lesion related to the vulvar rings (outer vulvar ring=4 points, middle vulvar ring=2 points, and inner vulvar ring=1 point), and,
- Specificity of the vulvar lesions (nonspecific lesions=2 points; specific lesions=14 points).

		NORMAL VULVA	IMPAIRED VULVAR SKIN (ASYMPTOMATIC)	VULVODYNIA	IMPAIRED VULVAR SKIN (SYMPTOMATIC)	VULVAR DERMATOSIS
<b>01</b>	<b>SYMPTOMS</b> Present=4 points	0	0	4	4	4
<b>02</b>	<b>DYSpareunia</b> (Marinoff index) Positive=3 points	0	0	3	0-3	0-3
<b>03</b>	<b>COTTON SWAB TEST</b> Positive=2 points	0-2	0-2	2	0-2	0-2
<b>04</b>	<b>LOCALIZATION</b> Outer ring=4 points Middle ring=2 points Inner Ring=1 point	0	1-7	1-7	1-7	1-7
<b>05</b>	<b>SPECIFICITY</b> Nonspecific=2 points Specific=14 points	0	2	2	2	14-16
	<b>SCORE (Points)</b>	<b>0-2</b>	<b>3-11</b>	<b>12-18</b>	<b>7-18</b>	<b>19-32</b>
	<b>MAIN FEATURES</b>	<ul style="list-style-type: none"> <li>Absence of symptoms</li> <li>Marinoff index negative</li> <li>No vulvar lesion except for slight vestibular erythema or papillae (normal).</li> </ul>	<ul style="list-style-type: none"> <li>Absence of symptoms</li> <li>Marinoff index negative</li> <li>Nonspecific vulvar lesion.</li> </ul>	<ul style="list-style-type: none"> <li>Diagnosis: Friedrich's criteria!</li> <li>Marinoff index and Cotton swab test positive</li> <li>Persistence of symptoms after local therapy</li> </ul>	<ul style="list-style-type: none"> <li>Akute vulvar discomfort</li> <li>Absence of specific vulvar lesion</li> <li>Disappearing of symptoms after local therapy <i>Patients excluded from the study!</i></li> </ul>	<ul style="list-style-type: none"> <li>Presence of lesions specific for dermatosis</li> <li>Often combined with nonspecific lesions</li> <li>Lesion of the vulvar skin (Outer &amp; Middle ring)</li> </ul>

Figure 3. Vulvoscopy Index.

Results of vulvoscopy were interpreted as follows:

- Normal vulva (0-2 points) was characterized by the absence of any symptoms and any vulvar lesions.
- Impaired vulvar skin was represented by a lack of vulvar discomfort and vulvoscopic findings of

nonspecific lesions (3-11 points).

- Vulvodynia (12-18 points) diagnosed by Friedrich's criteria always implies vulvar discomfort; nonspecific lesions found by vulvoscopy were irrelevant for the diagnosis of vulvodynia.

IV. Impaired vulvar skin with symptoms (7-18 points) included patients with acute vulvar discomfort and nonspecific lesions as well as vulvar inflammation and irritation. Vulvar symptoms disappeared after local treatment; these patients were excluded from the study.

V. Vulvar dermatosis (19-32 points) was recognized by the findings of a specific lesion or a combination of specific and nonspecific lesions in the presence of chronic vulvar discomfort.

### 2.3. Data Analysis

Statistical analysis was accomplished utilizing software packages StatSoft (Dell, Austin, Texas), Statistica 12 (TIBCO®, Palo Alto, CA), and SPSS 20 (IBM, Armonk, NY). Basic statistics were performed, including calculating the mean (the arithmetic mean, quartiles, mode) and measures of dispersion (variance, standard deviation).

A hypothesis that there would be differences among the distributions was also investigated. When the distribution of random variables was theoretically known, the appropriate parametric tests were used, and when the distribution was theoretically unknown, the proper nonparametric tests were used. The chi-square and Fisher's exact tests were used to measure the data on a nominal or ordinal scale. The t-test as a parametric test or the Mann-Whitney U test as a nonparametric test was used to test the difference in the distribution of the two continuous random variables.

### 2.4. Ethical Approval

All participants were advised that their participation was voluntary and reserved the privilege to decline to conduct the questionnaire. Patients provided written informed consent for vulvoscopy and vulvar biopsy. No encouragement was suggested for participation.

Ethical permission for this study was acquired from the Institutional Review Board of Polyclinic Harni, Ethical Approval Number 20111201001, as of December 1, 2011. The DATRIV study was registered at ClinicalTrials.gov Identifier: NCT02732145).

## 3. Results

Histopathological benchmarks for impaired vulvar skin and vulvodynia have not been specified, but the criteria for diagnosing vulvar dermatosis are well defined. Accordingly, the study participants were ordered into two categories for statistical analyses. The first group is called vulvar dermatosis. The second group was summoned absent vulvar dermatosis, for which we assembled participants with a diagnosis of the normal vulva, impaired vulvar skin, and vulvodynia. The diagnostic value of the vulvoscopy index was defined by comparing these two classes of patients.

To assess the correlation between vulvoscopy index and histopathological diagnosis, the scores of points (median and range), frequency and relative frequency of each separate item of the vulvoscopy index in both test groups were compared, as shown in *Tables 1 and 2*.

**Table 1.** Score (median and range) according to specific items of vulvoscopy index in patients with and without vulvar dermatosis diagnosed by vulvoscopy and histopathology.

Vulvoscopy index	Vulvar dermatosis		Mann-Whitney U test	Absent vulvar dermatosis		Mann-Whitney U test
	Vulvoscopy N=82	Histopathology N=72		Vulvoscopy N=246	Histopathology N=256	
	Median (Range) Mean ± S.D.	Median (Range) Mean ± S.D.		Median (Range) Mean ± S.D.	Median (Range) Mean ± S.D.	
1. Vulvar discomfort	4 (4-4) 4.0 ± 0.0	4 (4-4) 4.0 ± 0.0	-	0 (0-4) 1.33±1.89	0 (0-4) 1.44±1.92	NS
2. Marinoff index	0 (0-3) 1.28±1.49	0 (0-3) 1.29±1.50	NS	0 (0-3) 0.90±1.38	0 (0-3) 0.91±1.38	NS
3. Cotton swab test	0 (0-2) 0.68±0.95	0 (0-2) 0.67±0.95	-	0 (0-2) 0.85±0.99	0 (0-2) 0.84±0.99	NS
4. Localization of lesion	7 (2-7) 6.66 ± 1.08	7 (2-7) 6.72 ± 1.00	NS	1 (0-7) 1.86 ± 1.92	1 (0-7) 2.03 ± 2.09	NS
Outer vulvar ring	4 (0-4) 3.76±0.96	4 (0-4) 3.78±0.92	NS	0 (0-4) 0.29±1.04	0 (0-4) 0.42±1.23	N.S.
Middle vulvar ring	2 (2-2) 2.0±0.0	2 (2-2) 2.0±0.0	-	0 (0-2) 0.93±1.00	0 (0-2) 0.98±1.00	NS
Inner vulvar ring	1 (0-1) 0.90±0.30	1 (0-1) 0.94±0.23	NS	1 (0-1) 0.63±0.48	1 (0-1) 0.63±0.48	NS
5. Specificity of the lesion	16 (14-16) 15.73±0.69	16 (14-16) 15.75±0.67	NS	2 (0-2) 1.33±0.95	2 (0-16) 1.88 ± 2.93	NS
Nonspecific lesions	2 (0-2) 1.73±0.69	2 (0-2) 1.75±0.67	NS	2 (0-2) 1.33±0.95	2 (0-2) 1.34±0.94	NS
Specific lesions	14 (14-14) 14.0±0.0	14 (14-14) 14.0±0.0	-	0 (0-0) 0.0±0.0	0 (0-14) <sup>▲</sup> 0.55±2.72 <sup>▲</sup>	p=0.002**
Sum	28.5 (21-32) 28.35 ± 2.46	28.5 (21-32) 28.43±2.47	NS	5 (0-18) 6.27 ± 5.89	5 (0-32) 7.11 ± 7.15	NS

NS, not significant; \* p<0.05; \*\* p<0.01; \*\*\* p<0.001.

**Table 2.** Frequency of positive findings with respect to specific items of vulvoscopy index in patients with and without vulvar dermatosis diagnosed by vulvoscopy and histopathology.

Vulvoscopy index	Vulvar dermatosis			Absent vulvar dermatosis		
	Vulvoscopy N=82 (%)	Histopathology N=72 (%)	Mann-Whitney U test	Vulvoscopy N=246 (%)	Histopathology N=256 (%)	Mann-Whitney U test
1. Vulvar discomfort	82 (100%)	72 (100%)	NS	82 (33.3%)	92 (35.9%)	NS
2. Marinoff index	35 (42.7%)	31 (43.1%)	NS	74 (30.1%)	78 (30.5%)	NS
3. Cotton swab test	28 (34.1%)	24 (33.3%)	NS	104 (42.3%)	108 (42.2%)	NS
4. Localization of lesion	82 (100%)	72 (100%)	NS	163 (66.3%)	173 (67.6%)	NS
Outer vulvar ring	77 (93.9%)	68 (94.4%)	NS	18 (7.3%)	27 (10.5%)	NS
Middle vulvar ring	82 (100%)	72 (100%)	NS	115 (46.7%)	125 (48.8%)	NS
Inner vulvar ring	74 (90.2%)	68 (94.4%)	NS	156 (63.4%)	162 (63.3%)	NS
5. Nonspecific lesions	71 (86.6%)	63 (87.5%)	NS	163 (66.3%)	171 (66.8%)	NS
Specific lesions	82 (100%)	72 (100%)	NS	0 (0%)	10 (3.9%) <sup>▲</sup>	p=0.002**

NS, not significant; \* p<0.05; \*\* p<0.01; \*\*\* p<0.001.

There was no statistically significant difference between the scores of points, frequency and relative frequency of vulvar findings within one item of the vulvoscopy index and histopathology, except for the data labeled with <sup>▲</sup>, where the lesions specific for vulvar dermatosis were vulvoscopically visible. Nevertheless, histopathology did not confirm the diagnosis of vulvar dermatosis in these

patients at first biopsy. The diagnosis of vulvar dermatosis was histologically confirmed in six of these participants during the study course.

The sensitivity, specificity, and diagnostic accuracy of the vulvoscopy index for detecting vulvar dermatosis were 100%, 96.1%, and 96.9%, respectively. The positive and negative predictive values were 0.88 and 1.00, respectively (Table 3).

**Table 3.** Diagnostic accuracy of the vulvoscopy index in detecting vulvar dermatosis.

Histopathological diagnosis	Vulvoscopic diagnosis according to the vulvoscopy index	
	Vulvar dermatosis	Absent vulvar dermatosis
Vulvar dermatosis	72	0
Absent vulvar dermatosis	10	246
	Diagnostic value	
Sensitivity	1.0000	1.0000 – 1.0000
Specificity	0.9609	0.5794 – 1.0000
Accuracy	0.9695	0.6313 – 1.0000
Positive predictive value (PPV)	0.8780	0.2270 – 1.0000
Negative predictive value (NPV)	1.0000	1.0000 – 1.0000

NS, not significant; \* p<0.05; \*\* p<0.01; \*\*\* p<0.001.

## 4. Discussion

The importance of vulvar dermatosis stems from several well-substantiated facts. The aging of the world's population with the current state of 500 million or 8% of people over the age of 65, with a growing trend and anticipating this number to more than a billion people by 2030, is a major challenge in the medical profession [20]. Epidemiology is transforming, unsatisfactory health and mortality from non-contagious and chronic disorders in all world regions, reaching into focus [21]. This set of conditions also includes vulvar dermatoses, as inflammatory diseases that cause chronic or recurrent itching and discomfort in a limited area of the vulva are associated with extragenital localizations [22]. The most specific and particularly complex vulvar dermatoses are three vulvar lichens and Paget's disease due to difficulties in diagnosing early forms and delayed timely treatment and preventing vulvar cancer [23].

Extramammary Paget's disease (EMPD) is an infrequent skin disorder, most found in postmenopausal women close to 65 years of age, with an age-standardized incidence within Europe of 0.6 per 1,000,000 person-years. Female genitals

showed the highest increased risk of acquiring a second primary tumor after EMPD [24, 25].

Lichenoid vulvar disorders enclose lichen sclerosis (L.S.) and lichen planus (L.P.) as primary conditions and lichen simplex chronicus as secondary lichenification following itching. All lichens can negatively impact the quality of life. Additionally, L.S. and L.P. have an augmented hazard of squamous cell vulvar cancer [26].

Primary lichens have been predominantly diagnosed in postmenopausal women with the highest incidence between 65-69 years for L.P. (64/100,000) and between 75-79 years for L.S. (53/100,000) [27]. This population of women constitutes the bulk of the elderly. Women outnumber men globally, with 84 men for every 100 women aged ≥ 60 and 61 men for every 100 women aged ≥ 80 [28].

Women diagnosed with L.P. and L.S. had an increased hazard of vulvar cancer with a standardized incidence ratio (SIR) of 1.99 and 33.6, respectively. The risk for vaginal cancer is also grown in women with L.S. (SIR 3.69); however, the cervical cancer risk is decreased (SIR 0.00) [27].

The boost in postmenopausal women in the general population and the increase of vulvar dermatoses and vulvar



cancer is concerning. The incidence of L.S. increased from 7.4 to 14.6 per 100,000 women-years between 1991 and 2011, while the cumulative incidence of squamous cell carcinoma of the vulva was 6.7%. A Dutch study indicates an almost 100% gain in the incidence of L.S. between 1991 and 2011. Other reports suggest a 20-55% enlargement in the incidence of vulvar cancer in recent decades. Of particular importance for the development of vulvar cancer are the simultaneous finding of differentiated intraepithelial vulvar neoplasia (dVIN) and age  $\geq 70$  years at the time of diagnosis [29, 30].

Accordingly, endeavors to decrease vulvar cancer should concentrate on satisfactory identification and therapy of predecessor lesions, including vulvar dermatosis. To manage the challenges posed by an aged population, the present study suggests the need for a novel approach and greater individual involvement in observing and examining the signs of disease with growing incidence and thus personal contribution to reducing the costs of health care for older women.

A previous study has demonstrated that the classification of vulvar diseases following IFCPC and ISSVD principles from 2011 holds additional efforts in evaluating and organizing the therapy of vulvar lesions [8]. However, the concept of vulvoscopy was not modified or adjusted to new requirements. Some authors proclaimed that the vulvar colposcopy technique did not vary from the standard colposcopy of the cervix [6]. Others undermined the differences by stating that vulvoscopy is not a colposcopic assessment of the vulva [19].

An essential segment of the present work is to heighten consideration regarding developing suitable implements for evaluating test outcomes, as formerly advised [31]. Most of those tests are based on simple guidelines, so the first step in exploring a complex organ such as the vulva was to simplify the diagnostic procedure by organizing the structures of this organ into three rings.

Various measures of clinical value are associated with the diverse aspects of diagnostic techniques. The most common appraisals are exploited to estimate the test's discriminant property and predictive power. Health policy supports discriminatory measures, while predictive steps are most valuable in forecasting the likelihood of a disorder in an individual [32].

The introduction of TRIV could mark a turning point for this clinically important aspect of the vulvar examination. A simultaneous triple approach to the complex structure of the vulva deepens and refines prior knowledge of the different implications of identical lesions at various sites in this zone. The magnification applied in vulvoscopy makes it possible to distinguish altered epithelial structure and even changes in subepithelial elements, especially the presentation of blood vessels in the inner vulvar ring. In this way, the technique fulfills the principal doctrines of vulvoscopy.

Despite the straightforward presentation, mapping the lesions regarding the three vulvar rings did not reduce the acquisition of vast amounts of data by methodical examination of the vulva. The DATRIV study assessed the clinical value of the vulvoscopy index and the N-S-P scheme

as parameters of the TRIV outcome to facilitate data management and gain the possibility of measurability and comparison of vulvoscopy results.

The results of the DATRIV study are encouraging and could provide a qualitative shift in the differential diagnosis of vulvar lesions, particularly in detecting vulvar dermatoses.

Using the vulvoscopy index as an objective measure of the severity of vulvar disease/dermatosis of the vulva requires additional investigation and confirmation of the suitability of the test in the diagnosis and application in monitoring the improvement or worsening vulvar disease during treatment.

The current study also opens a wide area for new research that should examine the clinical value of vulvoscopy index in uncontrolled conditions, intra- and interobserver variability, the impact of education on TRIV performance and duration of the examination, faster patient triage and other aspects of clinical test value.

The difference between vulvoscopic and histopathological diagnostics, as shown in *Tables 1 and 2*, indicates the impossibility of histopathology in recognizing early forms of vulvar dermatoses due to lack of specific tissue changes, rather than the wrong biopsy site; however, this option cannot be ruled out. Histopathological changes in early dermatosis are absent or nonspecific; however, they have been described [33]. Hence, early dermatosis could represent a critical area for applying this test. Suppose it turns out that other researchers can diagnose early forms of vulvar dermatoses with this technique. In this case, a reassessment of the importance of histopathology as the gold standard in diagnosing early forms of vulvar dermatosis and paradigm shifts could be considered.

## 5. Conclusion/Recommendations

A new technique of examining the vulva using colposcopy called three rings vulvoscopy is proposed, considering three different skin types and zones that are almost ring-shaped and morphological evaluation of lesions according to their specificity (nonspecific and specific lesions).

The vulvoscopy index, an outcome measure of TRIV, showed a sensitivity, specificity, and diagnostic accuracy of 100%, 96.1%, and 96.9%, respectively, for detecting vulvar dermatosis, making it a compelling new clinical test in the diagnosis of vulvar dermatosis. Therefore, we suggest adopting the TRIV technique and further verifying the vulvoscopy index in clinical practice.

Additional investigations are required to check the importance of the vulvoscopy index in uncontrolled conditions, intra- and interobserver variability, the influence of education on the implementation and duration of examinations, and the application of the test in monitoring the improvement and worsening of vulvar dermatoses during treatment. Recognition of lesions present in early forms of vulvar dermatoses is a critical field for researching the value of this test.

## References

- [1] Micheletti L, Preti M, La Monica F. La vulvoscopy, no debe ser destinada como el examen colposcópico de la vulva. [Vulvoscopy should not be intended as colposcopic examination of the vulva.] *AMATGI* 2011; 4: 29-34.
- [2] McLean JM. Embryology and congenital anomalies of the vulval area. Chapter in Ridley CM. *The Vulva*. Edinburgh London Melbourne and New York, Churchill Livingstone; 1988: 1-38 and in Ridley CM, Neill SM. *The Vulva*. 2nd edition. Blackwell Science Ltd; 1999: 1-36.
- [3] McLean JM. Anatomy and physiology of the vulval area. Chapter in Ridley CM. *The Vulva*. Churchill Livingstone, Edinburgh London Melbourne and New York 1988; pp 39-65 and in Ridley CM, Neill SM. *The Vulva*. 2nd edition. Blackwell Science Ltd 1999; pp 37-63.
- [4] Neill SM, Lewis FM. Basics of vulval embryology, anatomy and physiology. Chapter in Neill SM, Lewis FM. *The Vulva*. 3rd edition. Blackwell Publishing 2009; 1-33.
- [5] Baggish MS. *Colposcopy of the cervix, vagina, and vulva: a comprehensive textbook*. 1st ed. Mosby, Elsevier; 2003.
- [6] Kesic V. Colposcopy of the vulva, perineum and anal canal. Chapter in Bosze P, Luesley DM. *EACG Course Book on Colposcopy*. Budapest, Primed-X-Press; 2003.
- [7] Byrne MA, Walker MM, Leonard J, Pryce D, Taylor-Robinson D. Recognising covert disease in women with chronic vulval symptoms attending an STD clinic: value of detailed examination including colposcopy. *Genitourin Med* 1989; 65: 46-9.
- [8] Bornstein J, Sideri M, Tatti S, Walker P, Prendiwill W, Haefner HK. 2011 Terminology of the Vulva of the International Federation for Cervical Pathology and Colposcopy. *J Lower Genit Tract Dis* 2012; 16: 290-5.
- [9] Foster DC, Stockdale CK, Simpson R, Kirtshhig G. Core Outcome Sets for Clinical Trials and Observational Studies in Vulvovaginal Disease. *J Lower Genit Tract Dis* 2017; 21: 163-5.
- [10] Harni V, Babic D, Barisic D. "Three Rings Vulvoscopy" – A New Approach to the Vulva. *Gynaecol Perinatol* 2015; 24: 37-45.
- [11] Harni V, Babic D, Barisic D. "Three Rings Vulvoscopy" – A New Approach to the Vulva. Chapter in Watson L (ed.) *Cryosurgery and Colposcopy: Practices, Outcomes, and Potential Complications*. New York, Nova Science Publishers Inc; 2016. ISBN: 978-1-63484-507-6.
- [12] van Beurden M, van der Vange N, de Craen AJM, Tjong-A-Hung SP, ten Kate FJW, ter Schegget J, et al. Normal findings in vulvar examination and vulvoscopy. *J Br Obstet Gynaecol* 1997; 104: 320-4.
- [13] Audisio T, Zarazaga J, Vainer O. A Classification of Vulvoscopy Findings for Clinical Diagnosis. *J Lower Genit Tract Dis* 1999; 3: 7-18.
- [14] Chren MM. Giving "scale" new meaning in dermatology: measurement matters. *Arch Dermatol* 2000; 136: 788-90.
- [15] Simpson RC, Murphy R. Considerations for Disease Impact and Outcome Measures in Vulvar Disease. *J Lower Genit Tract Dis* 2012; 16: 460-3.
- [16] ISSVD Vulvodysnia Pattern Questionnaire. Available at: <https://netforum.avectra.com/temp/ClientImages/ISSVD/3ef9c6ea-aac7-4d2b-a37f-058ef9f11a67.pdf> Last accessed May 23, 2015.
- [17] Haefner H, Collins M, Davis GD, Edwards L, Foster D, Hartmann E, et al. The Vulvodysnia Guideline. *J Lower Genit Tract Dis* 2005; 9: 40-51.
- [18] Stockdale CK, Lawson HW. 2013 Vulvodysnia Guideline Update. *J Lower Genit Tract Dis* 2014; 18: 93-100.
- [19] Bornstein J, Goldstein AT, Stockdale CK, Bergeron S, Pukall C, Zolnoun D, et al. 2015 ISSVD, ISSWSH, and IPPS Consensus Terminology and Classification of Persistent Vulvar Pain and Vulvodysnia. *J Lower Genit Tract Dis* 2016; 20: 126-30.
- [20] National Institute on Aging, National Institute of Health, U.S. Department of Health and Human Services. Why Population Aging Matters. A Global Perspective. *Publication No. 07-6134*. 2007.
- [21] Surveillance, Epidemiology, and End Results. SEER Cancer Stat Facts: Vulvar Cancer. National Cancer Institute. Bethesda, MD, <https://seer.cancer.gov/statfacts/html/vulva.html>.
- [22] Moyal-Barracco M, Wendling J. Vulvar dermatosis. *Best Pract Res Clin Obstet Gynaecol* 2014; 28: 946-58.
- [23] Doyen J, Demoulin S, Delbecq K, Goffin F, Kridelka F, and Delvenne P. Vulvar Skin Disorders throughout Lifetime: About Some Representative Dermatoses. *BioMed Research International Volume* 2014, Article ID 595286. DOI: <http://dx.doi.org/10.1155/2014/595286>.
- [24] van der Linden M, Meeuwis KA, Bulten J, Bosse T, van Poelgeest MI, de Hullu JA. Paget disease of the vulva. *Crit Rev Oncol Hematol*. 2016; 101: 60-74. DOI: 10.1016/j.critrevonc.2016.03.008.
- [25] van der Zwan JM, Siesling S, Blokk WA, Pierie JPEN and Capocaccia R. Invasive extramammary Paget's disease and the risk of secondary tumours in Europe. *EJSO*, 2012; 38: 214-221.
- [26] Fruchter R, Melnick L, Pomeranz MK. Lichenoid vulvar disease: A review. *Int J Womens Dermatol* 2017; 3: 58-64.
- [27] Halonen P. Lichen sclerosus and lichen planus in women. Incidence, risk of cancer and causes of death. Academic Dissertation, University of Helsinki, Helsinki 2020.
- [28] United Nations Population Fund (UNFPA), HelpAge International. Ageing in the Twenty-First Century: A Celebration and A Challenge. New York, London, 2012. ISBN 978-0-89714-981-5.
- [29] Bleeker MCG, Visser PJ, Overbeek LIH, van Beurden M, Berkhof J. Lichen Sclerosus: Incidence and Risk of Vulvar Squamous Cell Carcinoma. *Cancer Epidemiol Biomarkers Prev* 2016; 25: 1224-30.
- [30] Schuurman MS, van den Einden LC, Massuger LF, Kiemeny LA, van der Aa MA, de Hullu JA. Trends in incidence and survival of Dutch women with vulvar squamous cell carcinoma. *Eur J Cancer* 2013; 49: 3872-80.



- [31] Andrews JC, Bogliatto F, Lawson HW, Bornstein J. Speaking the Same Language: Using Standardized Terminology. *J Lower Genit Tract Dis* 2016; 20: 8-10.
- [32] Simundic AM. Measures of Diagnostic Accuracy: Basic Definitions. *Med Biol Sci* 2008; 22.
- [33] Regauer S, Liegl B, Reich O. Early vulvar lichen sclerosis: a histopathological challenge. *Histopathology* 2005; 47: 340-7.